

Atty. Dkt. No. 036481-0165

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Ralph BRAUN

Title:

NUCLEIC ACID

CONSTRUCTS FOR GENE

EXPRESSION

Appl. No.:

10/529,011

International

9/29/2003

Filing Date:

371(c) Date:

3/24/2005

Examiner:

Shen, Wu Cheng Winston

Art Unit:

1632

Confirmation

8838

Number:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b).

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Applicant does not waive any rights to take any action which would be appropriate to antedate or

otherwise remove as a competent reference any document which is determined to be a prima

facie art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the

mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicant respectfully requests that each listed document be considered by the Examiner

and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be

returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is

hereby authorized to charge any additional fees which may be required for this Request to Deposit

Account No. 19-0741.

Respectfully submitted,

Date Felosuary 20, 2007

By V.S. //
Richard C

Customer Number: 22428

Telephone: (202) 672-5483

Facsimile:

(202) 672-5399

Attorney for Applicant

Registration No. 35,792

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Approved for use through 03/31/2007. OMB 0651-0031

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Complete if Known U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

embstitute for form 1449/PTO INE RMATION DISCLOSURE TEMENT BY APPLICANT ate Submitted: February 20, 2007 (use as many sheets as necessary)

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Complete if Known					
Application Number	10/529,011				
Filing Date	9/29/2003				
First Named Inventor	Ralph BRAUN				
Art Unit	1632				
Examiner Name	Shen, Wu Cheng Winston				
Attorney Docket Number	036481-0165				

U.S. PATENT DOCUMENTS						
Examiner Cite Initials* No.1	Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant	
		Number-Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear	
	A1	US-5,057,540	10-15-1991	Kensil et al.		
	A2	US-5,171,568	12-15-1992	Burke et al.		
	A3	US-5,328,688	07-12-1994	Roizman		
	A4	US-5,378,814	01-03-1995	Houghton et al.		
	A5	US-5,865,796	02-02-1999	McCabe		
	A6	US-5,922,576	07-13-1999	He et al.		
	l					

	UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Application Document Serial Number-Kind Code ² (if known)	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		

			FOREIGN PATENT	DOCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	A7	WO 89/04669	06-01-1989	Chiron Corporation		
	A8	WO 90/11089	10-04-1990	Chiron Corporation		
·····	A9	WO 90/14436	11-29-1990	Chiron Corporation		
	A10	WO 92/16636	10-01-1992	Immunology Limited		
	A11	WO 93/18759	09-30-1993	Bayor College of Medicine		
	A12	WO 93/19768	10-14-1993	The Regents of the Univ. of California		
	A13	WO 94/12202	06-09-1994	University of Dundee		
	A14	WO 96/29421	09-26-1996	Cantab Pharmaceuticals Research Limited		
	A15	WO 96/40955	12-19-1996	Frank L. GRAHAM		
	A16	WO 98/21345	05-22-1998	The General Hospital Corporation		
	A17	WO 01/32221 A1	05-10-2001	Powderject Vaccines, Inc.		
	A18	WO 01/46449 A1	06-28-2001	Biovex Limited		

Examiner Signature	Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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036481-0165

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid QMB control number. Substitute for form 1449/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 10/529,011 STATEMENT BY APPLICANT 9/29/2003 Filing Date **First Named Inventor** Ralph BRAUN Date Submitted: February 20, 2007 Art Unit 1632 (use as many sheets as necessary) **Examiner Name** Shen, Wu Cheng Winston

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			FOREIGN PATENT	DOCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (<i>if known</i>)	try Code ³ Number ⁴ Kind MM-DD-YYYY App		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
:	A19	WO 01/46450 A1	06-28-2001	Biovex Limited		-
						+

Attorney Docket Number

		NON PATENT LITERATURE DOCUMENTS	
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	A20	BAER, R., et al., "DNA Sequence and Expression of the B95-8 Epstein-Barr Virus Genome", <i>Nature</i> , July 19, 1984, Vol. 310, pp. 207-211.	
	A21	BIXLER et al., "Synthetic Peptide Representing a T-Cell Epitope of CRM197 Substitutes as Carrier Molecule in a Haemophilus Influenzae Type B (HIB) Conjugate Vaccine", <i>Adv. Exp. Med. Biol.</i> , (1989), Vol. 251, pp. 175-180.	
	A22	CHEE, M.S., et al., "Analysis of the Protein-Coding Content of the Sequence of Human Cytomegalovirus Strain AD169", Current Topics in Microbiology and Immunology, (1990), Vol. 154, pp. 125-169.	
	A23	COFFIN, R.S., et al., "Herpes Simplex Virus-Based Vectors – Genetic Manipulation of the Nervous System", <i>Academic Press Limited</i> , (1996), ISBN 0-12-437165-5, pp. 99-113.	
	A24	DAVIS, et al., "CpG DNA is a Potential Enhancer of Specific Immunity in Mice Immunized with Recombinant Hepatitis B Surface Antigen" <i>The American Association of Immunologists</i> , 1998, <i>The Journal of Immunology</i> , (1998), Vol. 160, pp. 870-876.	
	A25	DAVISON, Andrew J., et al., "The Complete DNA Sequence of Varicella-Zoster Virus", <i>J. gen. Virol.</i> , (1986), Vol. 67, pp. 1759-1816.	
	A26	ERTL, C. J., et al., "Novel Vaccine Approaches", <i>The Journal of Immunology</i> , (1996), Vol. 156, pp. 3579-3582.	
	A27	FYNAN, E. F., et al., "DNA Vaccines: Protective Immunizations by Parenteral, Mucosal, and Gene-Gun Inoculations", <i>Proc. Natl. Acad. Sci. USA</i> , December 1993, Vol. 90, pp. 11478-11482.	
	A28	FYNAN, E. F., et al., "DNA Vaccines: A Novel Approach to Immunization", Int. J. Immunopharmac., (1995), Vol. 17, No. 2, pp. 79-83.	

Examiner	·	Date	
Signature		Considered	

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	Substitute for	form 1449/F	ото		Complete if Known
	INFORMATIO	N DISCLO	SURE	Application Number	10/529,011
	STATEMENT	BY APPLI	CANT	Filing Date	9/29/2003
1	Date Submitted:	Echruary 5	20. 2007	First Named Inventor	Ralph BRAUN
	Date Submitted.	rebluary a	20, 2007	Art Unit	1632
	(use as many sh	eets as ne	cessary)	Examiner Name	Shen, Wu Cheng Winston
Sheet	3	of	4	Attorney Docket Number	036481-0165

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T _€
	A29	HASSETT, D. E., et al., "DNA Immunization", <i>Trends in Microbiol.</i> , August 1996, Vol. 8, pp. 307-312.	
	A30	HOUGHTON, Michael, et al., "Molecular Biology of the Hepatitis C Viruses: Implications for Diagnosis, Development and Control of Viral Disease", <i>Hepatology</i> , (1991), Vol. 14, No. 2, pp. 381-388.	
	A31	IMOTO, M., et al., "Total Synthesis of Escherichia Coli Lipid A", Tetrahedron Letters, (1985), Vol. 26, No. 12, pp. 1545-1548.	
	A32	KILPATRICK, K. E., et al., "Rapid Development of Affinity Matured Monoclonal Antibodies Using RIMMS", <i>Hybridoma</i> , (1997), Vol. 16, No. 4, pp. 381-389.	
	A33	KILPATRICK, K. E., et al., "Gene Gun Delivered DNA-Based Immunizations Mediate Rapid Production of Murine Monoclonal Antibodies to the Flt-3 Receptor", of Murine Monoclonal Antibodies to the Flt-3 Receptor", <i>Hybridoma</i> , (1998), Vol. 17, No. 6, pp. 569-576.	
	A34	KRIEG, A. M., et al., "CpG Motifs in Bacterial DNA Trigger Direct B-Cell Activation", <i>Nature</i> , April 6, 1005, Vol. 374, pp. 546-549.	
	A35	LACHMANN, R. H., et al., "The Use of Herpes Simplex Virus-Based Vectors for Gene Delivery to the Nervous System", <i>Molecular Medicine Today</i> , September, (1997), Vol. 3, No. 9, pp. 404-411.	
	A36	LATCHMAN, D. S., et al., "Gene Delivery and Gene Therapy with Herpes Simplex Virus-Based Vectors", <i>Gene</i> , (2001), Vol. 264, pp. 1-9.	
	A37	MANICKAN, Elanchezhiyan, et al., "DNA Vaccines – A Modern Gimmick or a Boon to Vaccinology?", Critical Reviews in Immunology, (1997), Vol. 17, pp. 139-154.	
	A38	MCGEOCH, D.J., et al., "The Complete DNA Sequence of the Long Unique Region in the Genome of Herpes Simplex Virus Type 1", <i>J. gen. Virol.,</i> (1988), Vol. 69, pp. 1531-1574.	
	A39	MEDZHITOV, R., et al., "Innate Immunity: Impact on the Adaptive Immune Response", <i>Current Opinion in Immunology</i> , (1997), Vol. 9, pp. 4-9.	
	A40	MODROW, S., "Computer-Assisted Analysis of Envelope Protein Sequences of Seven Human Immunodeficiency Virus Isolates: Prediction of Antigenic Epitopes in Conserved and Variable Regions", <i>Journal of Virology</i> , Feb. 1987, Vol. 61, No. 2, pp. 570-578.	

Examiner	Date	
Signature	Considered	

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	STATEMENT BY A	APPLI	CANT	Filing Date	9/29/2003	
,	Data Submitted: Eab	uoni '	20. 2007	First Named Inventor	Ralph BRAUN	
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	A41	PAYNE, L. G., et al., "Poly[di(carboxylatophenoxy)phosphazene] (PCPP) is a Potent Immunoadjuvant for an Influenza Vaccine", <i>Vaccine</i> , (1998), Vol. 16, No. 1, pp. 92-98.				
	A42	PERTMER, T. M., et al., "Gene Gun-Based Nucleic Acid Immunization: Elicitation of Humoral and Cytotoxic T Lymphocyte Responses Following Epidermal Delivery of Nanogram Quantities of DNA", <i>Vaccine</i> , (1995) Vo. 13, No. 15, pp. 1427-1430.				
	A43	RAZ, E., et al., "Intradermal Gene Immunization: The Possible Role of DNA Uptake in the Induction of Cellular Immunity to Viruses", <i>Proc. Natl. Acad. Sci, USA,</i> September 1994, Vol. 91, pp. 9519-9523.				
	A44	THOMAS, S. K., "Herpes Simplex Virus Latency-Associated Transcript Encodes a Protein Which Greatly Enhances Virus Growth, Can Compensate for Deficiencies in Immediate-Early Gene Expression, and is Likely to Function During Reactivation from Virus Latency", <i>Journal of Virology</i> , August 1999, Vol. 73, No. 8, pp. 6618-6625.				
	A45	WOLFF, J. A., "Direct Gene Transfer into Mouse Muscle in Vivo", <i>Science</i> , March 23, 1990, Vol. 247, pp. 1465-1468.				
	A46	YANG, N-S, et al., "In vivo and in vitro Gene Transfer to Mammalian Somatic Cells by Particle Bombardment", Proc. Natl. Acad. Sci. USA, December 1990, Vol. 87, pp. 9568-9572.				

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